AstraZeneca

May 6, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Docket No. 2004D-0042**
Response to FDA Call for Comments
Draft Guidance for Industry on Improving Information About Medical Products and Health Conditions

Dear Sir or Madam:

Reference is made to the Federal Register Notice of February 10, 2004 announcing the availability of the **Draft Guidance for Industry on Improving Information About Medical products and health Conditions** – ***Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.***

AstraZeneca has reviewed the Draft Guidance document and we support the concept of "consumer friendly" approaches to satisfying the brief summary requirement in consumer-directed print advertisements to increase communication effectiveness. However, we believe that there are important issues that must be addressed prior to finalizing the document. AstraZeneca is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA) and we fully support the comments submitted by PhRMA on behalf of its member companies.

Many companies satisfy the brief summary requirement in consumer-directed print ads for prescription drugs by including the risk-related sections of approved professional labeling in its entirety. Although this approach fulfills the brief summary requirement, FDA also sees it as a less than optimal approach in the current prescribing environment. The February 10, 2004 Brief Summary Draft Guidance outlines two alternatives for providing the risk information that the FDA believes would be more accessible and more comprehensible to the consumer. However, as currently written, the draft Guidance poses important product liability issues for manufacturers. The three key areas of concern are described below:

- Neither of the proposed alternatives fulfills the currently applicable regulations requiring all of the risk information be included.

- In support of the described alternative approaches that FDA is proposing, the Guidance states "*FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the grounds that it does not present risk information in compliance with the brief summary requirement.*" Instead of clearly

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stating that the alternatives *would fulfill* the brief summary requirement, it notes that the FDA "does not intend to object" to the use of these alternatives. The messages are quite different, and as written, the Guidance describes "discretionary enforcement" on the part of the FDA in place of regulatory authorization

- The Brief Summary Guidance also poses a problem in that it clearly indicates fulfilling the brief summary requirement with verbatim risk information from the approved labeling is not the optimal approach and information delivered this way may be incomprehensible to consumers. While the proposed alternatives offer effective options in providing the risk information, AstraZeneca also believes there can be value in the provision of brief summary risk information using the approved prescribing information approach. The Guidance should be clear in pointing out that using this approach satisfies regulatory requirements and can also have value to the consumer.

To address these concerns, the FDA should:

a) Revise the Brief Summary Guidance to state that the alternative approaches described *fully* satisfy regulatory requirements for a true statement of information relating to side effects, contraindications, and effectiveness as described in 21 CFR 202.1. (This brief summary is required to contain information relating to each specific side effect, warning, precaution, contraindication, caution and special notes and considerations "contained in required, approved or permitted labeling for the advertised drug dosage form". The FDA should clarify in this guidance that "permitted labeling" includes safety information presented in accordance with the formats proposed in the Guidance, and found to be acceptable by the Agency for use. This definition of permitted labeling would allow patient-friendly safety information to be used to satisfy the regulatory requirement for a brief summary if that information was reviewed and found acceptable by the Agency, i.e. "permitted" labeling that was reviewed by DDMAC rather than through a formal approval in the NDA process).

b) Revise the Brief Summary Guidance to be clear that the provision of the brief summary risk information using the approved professional labeling continues to satisfy regulatory requirements *and* can be of value to the consumer.

c) Revise the brief summary regulations in 21CFR 202.1 to include reference to the alternative approaches of providing DTC risk information as outlined in the draft guidance. On the heels of FDA's own studies and the September 2003 hearings, the value potential of DTC advertising to healthcare professionals and patients is clear, and appropriate support for DTC advertising in the regulations is warranted.

In addition, there are several operational approaches that FDA could adopt which would help manufacturers with the development and implementation of consumer-friendly brief summary risk information:

- Risk information derived from FDA approved patient labeling or "Highlights" Labeling should have a high review priority to enable the appropriate distribution of useful information in a timely manner.

- The Agency should consider developing listings of "acceptably consumerized" medical terms and descriptions that would help manufacturers in their translation of professional labeling

- The agency should consider how it would handle issues of consistency? As written, the Guidance suggests that use of the "Highlights" approach would not actually require prior approval of the consumer-friendly language from FDA, leaving the door open for inconsistent descriptions of the same risk information. This could be especially problematical with drugs that have class labeling risk information.

Comment on Other Approaches to Providing Risk Information

While the concept of providing a risk information window might be applicable in some cases, it is clear that it would be practical for all drugs due to lack of space. FDA's suggestion to put risk information in both the risk window and in the body of the text for drugs needing more space could be counterproductive. Alerting consumers to look at the risk window box may come with some expectation on the part of the consumer that *all* of the safety information is included there. That may be all they look at. There should be extensive testing of the "window" approach to be certain that the reader does not dismiss the importance of the information (e.g. similarity to a Nutritional Information Box, always there so you stop looking at it like Surgeon General's Warning on cigarettes).

With respect to the Agency's question regarding the incorporation of risk information into the body of the advertisement, obviating the need for disclosure elsewhere (brief summary), it would seem that some drugs could be handled this way, but it might be confusing to the consumer who has come to expect some sort of a "brief summary" page.

Another option would allow the risk information to be disclosed in the brief summary on a page which must be facing the advertising copy. If laid out this way, no additional risk information would be required in the text of the ad.

AstraZeneca appreciates the opportunity to provide comments for consideration during the development of this Guidance document. Please do not hesitate to contact us should you have any questions.

Sincerely,

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